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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,899	03/23/2005	Tatsuo Hoshino	K21402USWOC038435/0185657	4162
7590 Stephen M Haracz Bryan Cave 1290 Avenue of the Americas New York, NY 10104			EXAMINER ARIANI, KADE	
			ART UNIT	PAPER NUMBER
			1651	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/09/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,899	<b>Applicant(s)</b> HOSHINO ET AL.	
	<b>Examiner</b> Kade Ariani	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                 | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### Detailed Action

Claims 1-9 are presented for examination.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hancock et al. (FEMS Microbiology Letters, 2000, Vol.186, p.245-250).

Claims 1-3 are drawn to a process for the production of L-aldonolactone from L-aldohexose by a microorganism capable of producing L-aldonolactone from L-aldohexose, and, optionally, isolating the L-aldonolactone from the reaction mixture, wherein the L-aldonolactone is selected from the group consisting of L-gulono- 1,4 -lactone, L-gulonic acid, L-galactono- 1,4 -lactone, and L-galactonic acid, the L-aldohexose is selected from L-gulose or L-galactose.

Art Unit: 1651

Claims 7 is drawn to the process of claim 1 wherein the microorganism is used in a growing culture or a resting cell reaction,

Hancock et al. discloses the process of claimed invention wherein a growing culture of *Saccharomyces cerevisiae* produce L-galactono- 1,4 –lactone (L-aldonolactone) from a L-galactose (L-aldohexose)(p. 245, abstract, p. 248, Col.1 Lines 24-33, also Fig.1), *S. cerevisiae* cultures were grown to mid-exponential phase (p.246, Col.1, 3<sup>rd</sup> paragraph, 1<sup>st</sup> line). Hancock et al. therefore clearly anticipates the claimed invention.

Claims 1-3 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Porro et al. patent application publication No. US 2005/0260722 A1 (Pub. Nov. 24, 2005, Filed 06/25, 2003).

As mentioned above, Porro et al. discloses a method for the production of L-galactono- 1,4 –lactone (L-aldonolactone) from L-galactose (L-aldohexose) by culturing a yeast species in a medium (Abstract, p. 2, 3, and 4, 0025,0031, 0039, also Fig.1 and Fig.4), isolation of the final product from the medium (p.4, 0042, and 0043). Porro et al. therefore clearly anticipates the claimed invention.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1651

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinjoh et al. (Applied and Environmental Microbiology, 1995, Vol.61, No.2, p.413-420), in view of Smirnoff et al. (Annu. Rev. Plant Physiol. Plant Mol. Biol., 2001, Vol. 52, p.437-67) and further in view of and further in view of Hancock & Viola (TRENDS in Biotechnology, July 2002, Vol.20, No.7, p.299-305).

Claims 1-9 are drawn to a process for the production of L-aldonolactone from L-aldohexose by a microorganism capable of producing L-aldonolactone from L-aldohexose, and, optionally, isolating the L-aldonolactone from the reaction mixture, wherein the L-aldonolactone is selected from the group consisting of L-gulonolactone, L-gulonic acid, L-galactonolactone, and L-galactonic acid, the L-aldohexose is selected from L-gulose or L-galactose, wherein the microorganism is selected from *Pseudomonas* or *Gluconobacter*, wherein the microorganism is *Pseudomonas putida* or *Gluconobacter oxydans*, wherein the microorganism is *P. putida* ATCC 21812 or *G. oxydans* IFO 3293, the process wherein the microorganism is used in a growing culture or a resting cell reaction, the process is conducted for 1-120 h at a pH in the range of about 1 to about 9 and a temperature in the range of from about 13°C to 45°C, and the process is conducted for 1-120 h at a pH in the range of about 2 to about 8 and a temperature in the range of from about 18°C to 42°C.

Shinjoh et al. recites a method of converting L-sorbose to L-sorbosone by a genetically modified strain of *G. oxydans* IFO 3293 (p. 413, abstract, and Col.2, last

Art Unit: 1651

paragraph, also p.414, Col.1, Lines 1-4), by resting and growing cells (p.414, Col.2, Lines 2), *G. oxydans* were grown at 30°C, for 48 h (p.415, Col.1, Lines 31-33).

Shinjo et al. does not recite L-galactose, and L-galactono-1,4 –lactone, and at a pH in the range of from 1 to about 9 or at a pH from 2 to about 8. However, Smirnoff et al. discloses a novel enzyme L-galactose dehydrogenase that oxidizes L-galactose to L-gactono-1, 4 -lactone (p.441 and 422, Lines 5-6, Fig.1 reaction 7) has been purified and cloned, L-galactose dehydrogenase recognizes L-gulose, L-sorbose and L-fucose, with a 45% similarity to the amino acid sequence of *Pseudomonas* L-fucose gehydrogenase. (p.444, Last paragraph, p.445, 1<sup>st</sup> paragraph).

Hancock & Viola recites “genetic engineering has been used in strain improvement to enhance yields ... *Gluconobacter oxydans* is the species of choice for this purpose...” (p.300, Col.1, 2<sup>nd</sup> paragraph, Lines 1-2, and Col. 2, Lines 1-2), “recent resolution of the primary L-ascorbic acid pathway in higher plants will offer additional tools for process improvement via genetic engineering” (p.302, lines 27-30) and further recites “ yeast cells are known to accumulate L-ascorbic acid when grown in the presence of non-physiological substrates L-gulonolactone, L-galactonolactone or L-galactose (p.303, Col.1, 2<sup>nd</sup> paragraph, Lines 12-15). Hancock & Viola recites L-galactose and L-galactonolactone as a cheap source of starting substrate (p.303, Col.2, Lines 2-3) and further discloses “the isolation of genes involved in L-ascorbic acid biosynthesis in plants might provide useful biochemical tools to extend the metabolic capacity of industrial microorganisms (p.303, Col.2, Lines 8-12).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to use the enzyme taught by Smirnov et al. in the method of Shinjoh et al. in order to obtain a recombinant bacterial strain that has the ability to convert L-galactose to L-galactono-1, 4-lactone. One would have been motivated to use the enzyme disclosed by Smirnov et al. in the method of Shinjoh et al. to obtain a strain of *G. oxydans* or *P. putida* capable of converting L-galactose or L-gulose to L-galactono-1, 4-lactone or L-gulonolactone since it has been well known in the art at the time the invention was made that genetically engineered microorganisms can be used to convert intermediates of L-ascorbic acid pathway also genes involved in L-ascorbic acid biosynthesis in plants might provide useful biochemical tools to extend the metabolic capacity of industrial microorganisms at the same time L-galactose and L-galactonolactone are cheap substrates. Therefore, it would have been obvious to use the method disclosed by Shinjoh et al. using the enzyme recited by Smirnov et al. to obtain a strain of *G. oxydans* IFO 3293 which is able to convert the claimed substrate(s) to the claimed product(s).

Accordingly, the invention taken as whole is *prima facie* obvious.

### Conclusion

No claims allowed.

Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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